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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/676,046
Filing Date: September 30, 2003
Appellant(s): WHITMAN, MICHAEL P.

Clifford A. Ulrich
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 18, 2009 appealing from the Office action mailed April 16, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

WO 93/15648	WILK et al.	08-1993
Re. 36,434	HAMLIN et al.	12-1999
4,884,133	KANNO et al.	11-1989

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-4, 6-8, 10-32, 34, 36-58, 60-64 and 66-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk et al. (WO 93/15648) in view of Hamlin et al. (Re. 36,434) and further in view of Kanno et al. (U.S. Pat. 4,884,133).

With respect to claim 1, Wilk et al. disclose a shaft (14, Fig.1,3) having a proximal end and a distal end (Fig.1), an image capture device (CCD 90, Fig.4; or 152, Figs.7,8)[1] configured to receive image data from the distal end of the shaft, a light source (26, 34,Fig.1,3; or 160, Fig.7) configured to provide light at the distal end of the shaft, wherein the image capture device and the light source are mounted at the distal end of the shaft (Figs.1,3,4).

As for the shaft being sealed (i.e., "an interior of the shaft having a fluid-tight seal from the environment at the distal end and the proximal end so as to be sterilizable for re-use" and the

[1] When discussing the fluid tight nature below with respect to Figures 1 and 3, it is importantly noted that although Figure 4 is used to demonstrate the image capture device as being a CCD, the shaft (82) and optical guide (80) of Figure 4 are analogous to shaft (14) and optical guide (20) of Figures 1 and 3 and therefore, all teachings from one embodiment apply to the other.

image capture device and light source being "fluid-tightly sealed from the environment by the shaft so as to be sterilizable for re-use"), Wilk et al. teaches that the channel (in shaft 14) that receives the optical guide member (20) is "closed at the distal end" (page 5, fourth full paragraph) (note window 28 in Figure 3 for example) and that the "present endoscope is easier to clean and maintain in a sterile condition" (page 5, fifth full paragraph). This suggests to the reasonable person that window seals the shaft, otherwise the optical guide member (20) would not remain in a sterile condition. Since the claimed subject matter sets forth the condition for being "sterilizable for re-use" as being "fluid tightly sealed", at least the sealed shaft will meet this limitation. It is noted that the optical guide member (20) would also appear to be sealed at least at the distal end, and thus, sterilizable. There is no reason to believe that any portion of the Wilk et al. device could not be sterilized or autoclaved, even though that might not be intended.

Clearly, regarding the citations in Wilk et al. from the paragraph immediately above, the sterility must also depend not only on the sealed window, but the shaft (tube 14) itself (a window sealed with the shaft would have no more effect that one that is not, if the shaft itself is not sealed). Keeping the optical guide member in a sterile condition (while the device is inside of a body) would inherently require the material making up the outside of the tube to be "fluid-tight", if not "air-tight".

Although it would appear to be inherent that the proximal end (coupling element 50) of tube (14) is connected to control module (12) in a sealed manner to maintain the sterile condition of the elements on the interior, as pointed out above, Wilk et al. fails to explicitly state this. Hamlin et al. teach in the relevant field of endeavor to place a sealed, sterilizable or discardable tube (18) over an optical guide member (12) such that the connection of the tube to the control

module (10) is sealed (note Figs.3, 4 and 7, and col. 6, lines 1-9). This prevents contamination from entering the interior of tube (18) and thus contamination of the optical guide member (12) (col.6, lines 4-9). It would have been obvious to one of ordinary skill in the art, if not already inherent, to have similarly sealed the proximal end of the tube (14) of Wilk et al. when connected to the control module (12) to prevent contamination from entering the interior of the tube. This is consistent with the teaching of Wilk et al. to maintain the optical guide member in a sterile condition. Such modification thus providing an interior of the shaft having a fluid tight seal from the environment at the distal (as previously pointed out) and proximal ends.

Wilk et al. in view of Hamlin et al. disclose the elements as set forth above including a light source but fails to specify the nature of the light source. Kanno et al. demonstrates that it is known to use an LED or an array of LEDs in an endoscope for providing illumination light (note 26G, 26R, 26B of Figure 1(c) for example). Since it is well known and well within the ordinary skill in the art to recognize the advantages of LEDs (e.g., low power requirements, small size, etc.) over normal incandescent lamps and use of LEDs in an endoscope for the same purpose as Wilk et al. (i.e., illumination) has been previously contemplated, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used LEDs for the generic "light source" of Wilk et al.

Regarding all other claims, Wilk et al. disclose a control module (12, Fig.1), and a power module (38) which can include a integrally housed power source (260, Fig.12). All components of Wilk et al. are "sterilizable" and "autoclavable" since everything is "sterilizable" and "autoclavable" (and the inherent size of the Wilk et al. device would allow for the device to fit inside any known machine for doing either). The shaft (14) is bendable using steering cables

(72a,72b,74a,74b, Fig.2), and is thus flexible, and the steering cables are connected to motors (252,254,Fig.12). The light source and image capture device can be mounted at the distal end of the shaft (Figs.7 and 8) and the distal light source can include a second power source (158, Fig.8) at the distal end of the shaft. The control module includes a video processor (not numbered but inherent in the circuitry associated with the CCD for supplying the video monitor (32), page 7, last paragraph) and a integrally mounted display screen (32). The shaft includes channels (52a,52b,52c) which are capable of conveying fluid or providing suction (60c,60a). Any of these channels can permit the passable of tools through the shaft. The shaft further includes a data transfer cable (88,Fig.4) for transmitting data to the video processor. The control module includes a control unit (any one of the housing for manually manipulating the device, the joystick (104, Fig.5), the buttons shown on the side of the display (Fig.5), or any of the controls of the suction source, air source, water source or light source) and a controller (any one of the electrical or mechanical means that control the suction source, air source, water source and light source, the processing circuitry which delivers an image to the display, motors (252,254), wireless transmitter (156,Fig.8), etc.). Since almost anything can be hand-held, the device of Wilk et al. is configured to be. The device of Wilk et al. is intended to be placed within the body so, as best understood, it is configured as an endoscope, proctoscope and anoscope.

(10) Response to Argument

Appellant has limited his arguments to similar claim limitations that are found in each of independent claims 1, 29 and 56. In view of the entered After Final Amendment (Amendment filed October 16, 2008 and entered by Advisory Action mailed October 31, 2008), claim 29 is

identical to claim 1[2]. Claim 56 includes the argued limitations with additional limitations. However, claim 56 is not argued separately with respect to the additional limitations. Thus, all claims are argued as a group and appear to stand or fall together. Since claim 1 is representative of the issue at hand and Appellant concentrates his arguments on the language of claim 1 (note page 4, fourth full paragraph under Argument section of the Appeal Brief wherein claims 29 and 56 are grouped with claim 1 with respect to their similar limitations), the Examiner will focus his remarks on claim 1.

It appears from Appellant's arguments that there are **two issues** in dispute:

1) *Whether Wilk et al. teaches a device that is "fluid-tightly sealed from the environment by the shaft so as to be sterilizable for re-use"* (note page 5, first and second full paragraphs of the Appeal Brief); and

2) *Whether it would be obvious to use a LED mounted at the distal end in the Wilk et al. device in view of Kanno et al.* (note page 4, third full paragraph under the Argument section to line 3 of page 5)

It is noted that Appellant does not argue the merits of the combination of Wilk et al. and Hamlin et al. in light of the first issue, since if the shaft of Wilk et al. is not fluid-tightly sealed from the environment, then whether or not the proximal end of the shaft is sealed as it connects to the control module is actually inconsequential.

Furthermore, the Examiner takes the position that if the first issue is evidenced to be true, then the light source of Wilk et al., no matter whether it is a LED or a conventional light bulb

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[2] In a normal Office Action, Applicant is giving a warning that identical claims in an application will be objected to under 37 CFR 1.75 if the claims are found to be allowable. Since neither claims 1 or 29 were found to be allowable, no objection was warranted, and entering the After Final Amendment of October 16, 2008 did materially simplify

and optical fiber, will automatically be "fluid-tightly sealed from the environment by the shaft so as to be sterilizable for re-use" since the light source of Wilk et al. is contained within the shaft.

Issue 1

The Examiner takes the position that he has adequately set forth in the rejection a logical reasoning, drawn from evidence suggested in Wilk et al., that the entirety of shaft (14) (Figs.1,3) is contemplated to be fluid-tightly sealed from the environment. Wilk et al. admits that:

the distal end of the shaft (14) is "closed at the distal end" (page 5, fourth full paragraph; note "insertion tube" is referring to shaft 14);

the "present endoscope is easier to clean and maintain in a sterile condition" (page 5, fifth full paragraph); and

"Upon the termination of the operation, insertion tube 14 and optical guide member 20 are withdrawn from the patient. Insertion tube 14 is then detached from control module 12 and optical guide member 20 is removed from insertion tube 14. Insertion tube 14 is discarded, while control module 12 and optical guide member 20 are ready for immediate use with another disposable insertion tube 14" (page 9, lines 1-7).

The Examiner takes the position that it is impossible (or maybe just irresponsible) to re-use optical guide member (20) in another patient if insertion tube (14) did not maintain the sterility of optical guide member (20). And to maintain the sterility, the insertion tube (14) can not be allowed to pass at least fluids, if not gases, to the optical guide member (20) since both fluids and gases are present inside a patient.

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the issues for appeal by reducing the issues to a single obviousness rejection, the Examiner took the position the

Thus, although Wilk et al. does not use the words "fluid-tight", evidence in the disclosure of Wilk et al. explicitly suggests, to the reasonable person, that, to keep the optical guide (20) sterile, shaft (14) inherently has to be fluid-tight. As pointed out in the rejection, the condition for being "sterilizable for re-use" is defined as being "fluid-tightly sealed from the environment". Furthermore, it would not be unreasonable to assume that all components are sterilized at least once before use since no practitioner would knowingly insert an unsterile device into a patient.

Appellant believes that Wilk et al. teaches away from the shaft being fluid-tightly sealed from the environment so as to be sterilizable for re-use (page 5, first and second full paragraphs of Brief). To this, Appellant points out that Wilk et al. states "[t]here is no need to subject optical guide member 20 to sterilizing and cleaning operations which may damage the optical guide and eventually wear it down" (page 9, lines 7-10 of Wilk et al.). Appellant would probably be correct if our dispute was over a method claim that recited a step of actively sterilizing the shaft. HOWEVER, it is shaft (14) of Wilk et al. that the Examiner has evidenced is fluid-tightly sealed from the environment so as to be sterilizable for re-use (note the Examiner's rejection and remarks made immediately above). EVEN IF the Examiner is relying on optical guide member (20) as being fluid-tightly sealed and thus sterilizable, the Examiner takes the position that Wilk et al. does indeed suggest the capability of optical guide member (20) being sterilizable, just not the intention of such. Note that if optical guide member (20) is sterilized, damage MAY occur and it MAY EVENTUALLY wear down. This would suggest to the reasonable person that the optical guide member (20) CAN be sterilized, but it is just not suggested to do so many times due to eventually failure in structural integrity.

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amendments to claim 1 and 29 were acceptable.

Although Appellant mentions Hamlin et al. regarding "teaching away" from the "sterilizability" feature of claim 1, the Examiner does not rely on Hamlin et al. for this feature and thus this point is rendered moot.

Issue 2

With respect to Wilk et al., the Examiner pointed to elements (34,26) in Figures 1 and 3 as showing a light source and element (160) in Figure 7 as showing an alternative light source where the source of light is located at the distal end. It is noted that the light source in Figures 1 and 3 is being considered to encompass both the source of light (34) and the optical fiber (26) since it requires both to transmit light from the distal end of the shaft.

Appellant argues that replacing the light source[3] in Figure 1 of Wilk et al. with a light emitting diode (LED) would not teach or suggest a LED mounted at the distal end of the shaft and fluid-tightly sealed from the environment by the shaft (note last paragraph of page 4 of Appeal Brief). The Examiner agrees.

Appellant further argues that replacing light source (160) of Figure 7 of Wilk et al. with a LED would not teach or suggest a LED mounted at the distal end of the shaft and fluid-tightly sealed from the environment by the shaft (note last paragraph of page 4 of Appeal Brief). The Examiner respectfully disagrees with this assertion. Light source (160) is already at the distal end of the shaft. Using a specific type of source, e.g., an LED as taught by Kanno et al., for the generic light source of Wilk et al.[4] would not change the fact that it is located at the distal end.

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[3] It is assumed that Appellant is referring only to element 34 and not element 26.

[4] Wilk et al. does not teach any particular type of source of light, e.g., incandescent bulb, halogen, LED, laser diode, etc.

Appellant further argues that, as to the Examiner's suggestion to replace the optical fiber with a LED, it would be unclear how this would be done (note last sentence on page 4 to end of first paragraph on page 5). The Examiner agrees because this doesn't make any sense. Instead, Kanno et al. teaches that use of LEDs at the distal end (note 26R,26B,26G in Fig.1c) takes the place of BOTH the optical fiber (which is only acting as a transmission means) and the source of light (note lamp 37 is required in the embodiment of Kanno et al. that uses optical fiber 23, Fig.1b, but is not required when LEDs are place at the distal end). It is noted that the Examiner expressly cited the Kanno et al. reference, not only because it evidences ordinary skill in using LEDs at the distal end of an endoscope, but also because it shows the alternative light source configuration (proximally located source of light which uses optical fibers to transmit to light to distal end; see Figure 1b of Kanno et al.) disclosed by Wilk et al.

Regarding Appellant's assertion (note last full paragraph of page 5 to first full paragraph of page 6 of Appeal Brief) that the Examiner did not use any of the example rationales set forth in *KSR International Co. v. Teleflex Inc.* (127 S. Ct 1727, 82 U.S.P.Q. 2d 1385, 2007) (hereinafter 'KSR'), the Examiner notes that he is not required to use the template wording for each rationale of KSR. Kanno et al. evidences known structure which could easily fall into the 'simple substitution' rationale, or the 'combining prior art elements according to known methods to yield predictable results' rationale. However, the Examiner takes the position that since Kanno et al. provides teaching, suggestion and motivation in the endoscope art that would have led one of ordinary skill to modify Wilk et al. to include a LED light source at the distal end, use of additional rationales are unnecessary and redundant.

For the foregoing reasons, the Examiner takes the position that the combination of Wilk et al., Hamlin et al. and Kanno et al. does render claim 1 unpatentable and specifically makes obvious a light emitting diode mounted at a distal end of the shaft and fluid-tightly sealed from the environment by the shaft so as to be sterilizable for re-use.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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